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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/852,472 | 05/10/2001 | Paul O. Sheppard | 97-28C1 | 6027 |

7590 06/06/2005

| EXAMINER |
|---|
| PAK, MICHAEL D |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

Paul G. Lunn, Esq.
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 09/852,472 | **Applicant(s)** SHEPPARD ET AL. | |
|---|---|---|---|
| | **Examiner** Michael Pak | **Art Unit** 1646 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 03 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on *03 August 2004*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *16-34*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Michael D. Pak
MICHAEL PAK
PRIMARY EXAMINER

Continuation of 3. NOTE: Newly amended claim limitation requires additional consideration and search because the diagnostic assay limitation was not specifically claimed previously.

Continuation of 5. Applicant's reply has overcome the following rejection(s): 5. The rejection of claiims 18, 21, 24, and 28-34 under 35 U.S.C. 112, first paragraph has been overcome .

Continuation of 11. does NOT place the application in condition for allowance because: the newly amended claims have not been entered and the previous rejection addressed the previous claims. Applicants argue that subsequent RT-PCR analyses of Zneul expression using CDNA tumor panels and matched CDNA pairs from tumor and normal tissues indicates that Zneul is up-regulated in tumor tissues and is not up-regulated in normal tissues. Therefore,applicants assert that Zneul would be suitable for use as a diagnostic cancer marker and specification specifically describes Zneul's use as a diagnostic cancer marker: However, no evidence has been presented regarding the diagnostic use of the Zneu except for the arguments by applicants regarding the experiments. Furthermore, at the time of the invention, the specification on page 28 state that Zneu may play other roles in cancer cells such as breast cancer because of the roles played by EGF in breast cancer. Thus, at the time of the invention one skilled in the art was not aware of the function of the orphan protein, Zneu. Applicants continue to argue that homology is sufficient for utility. However, Zneu1 polypeptide is an orphan polypeptide whose function has not been elucidated. Thus, any future experimentation is empirical experimentation for which the function of the orphan protein must be determined and not known at the time of the filing of the application. Furthermore, the specification on page 28 (lines 11-12) teaches that Zneu1 may have nothing to do with Notch and many proteins have EGF repeats. The claimed polypeptides do not have substantial utility because different growth factors with similar homology have different functions and the a skilled artisan would have to determine the function of the growth factor. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. Brenner V. Manson 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966).